

REMARKS

Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-34 are pending in the application.

Claims 1, 5-13, 19, 20, 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Jie et al. (Am J Clin Nutr 2000, 72:1503-9) ("Jie"). Claims 1, 5-14, 16-19, 27, 28, 30, and 32-34 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Takemori et al. (US 5,711,982, January 27, 1998) ("Takemori"). Claims 1, 5-14, 16, 17, 19, 24, 26-28, 30, and 32-34 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Shaw Craig et al. (US 2003/0008843, January 9, 2003). Claims 1, 5-13, 19, 27, and 28 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Solomons et al. (J. Lab. Clin. Med, May 1985, pages 585-592) ("Solomons"). Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomons in view of Borden et al. (US 5,601,863, February 11, 1997).

Claims 1, 5, 8-13, 16 and 32-33 are amended. The amendments to claims 1 and 5 are described below in the Preliminary Remarks. The amendments to claims 8-13, 16 and 32-33 were amended to either remove references to "preventing" (see claims 8-13 and 16), or, to conform the use of the term "synergistic" to proper English usage (see claims 16, 32-33).

The foregoing amendments and ensuing remarks address each of the Examiner's rejections in the sequence set out in the Office Action of July 25, 2008. No new matter has been added.

Preliminary Remarks

Although Applicants respectfully disagree with the rationale underlying the rejections, and in order to expedite the allowance of the claims, the preamble of independent claim 1 has been amended. The preamble to claim 1 now specifies that the claimed method is drawn to therapeutically treating a subject experiencing uncontrolled accumulation of lactic acid

in the colon. The support in the specification for this amendment is provided on page 9, text lines 15-16. Further, as described below, it is respectfully submitted that none of the cited references expressly or inherently disclose such a method of therapeutic treatment.

Claim 1 was further amended by adding a limitation to the body of the claim specifying that the uncontrolled accumulation of lactic acid is indicative of imbalanced colon fermentation. Support for this claim limitation is found in the specification on page 9, lines 15-18. Accordingly, no new matter has been introduced in the amended claims.

Jie teaches that polydextrose ingestion is accompanied by an increase in the levels of short chain volatile fatty acids (VFAs) in the colon (Jie, Abstract). Butyric acid is the most abundantly increased VFA in this context. However, it is noteworthy that the instant specification discloses that the production of a different short chain carboxylic acid, i.e., lactic acid, is almost completely shut down (Specification, Example 2, discussed below). Thus, the therapeutic effect of the method of the present invention is founded in a specific metabolic process wherein lactic acid production is greatly reduced. None of the references explicitly or inherently disclose or suggest this claimed method.

Dependent claim 5 depends from newly amended claim 1. Claim 5 has been amended by deleting the term "without accumulation of lactic acid" in view of the language added in currently amended claim 1. Therefore, this amendment does not introduce new matter into the specification.

Applicants respectfully submit that none of the cited references taken individually, or in combination, teach or suggest a method of treating a subject suffering from uncontrolled accumulation of lactic acid resulting from imbalanced colon fermentation.

Accordingly, it is respectfully submitted that the instant application is in condition for allowance.

Rejection Under 35 U.S.C. § 103(a)

Page 2 of the Advisory Action dated October 15, 2008 provided the following explanation as to why the amended claims allegedly did not overcome the prior art:

Although the cited references are silent regarding imbalanced colon fermentation, the definition of "imbalanced fermentation" in the instant specification does not distinguish the claims from the patient populations taught in the prior art. ... Sensitivity to nutrients or inflammation can lead to imbalanced fermentation, as can use of proteins as an energy source Because the definition of imbalanced colon fermentation is so broad, subjects suffering from such can be considered any subject. Thus, Applicant's amendment does not overcome the prior art rejections of record. (Emphasis added).

Although Applicants respectfully disagree with this rationale, the currently amended claims are now specifically drawn to a method of treating a specific disorder of the colon – uncontrolled lactic acid accumulation. This is a specific condition that can result from imbalanced colon fermentation. As described below, none of the references refer to this specific condition, and neither is the specifically defined target patient group disclosed. Accordingly, it is believed that the amendments submitted herewith effectively address the Examiner's concerns.

The studies by Jie are directed to determining the safety of polydextrose as a bulking agent (Jie, page 1503, col. 2) and does not disclose the claimed disorder or patient group. It is of interest that Jie discloses that they observed that polydextrose caused an increase of bacteria of the genus *Lactobacillus*, which would be expected to provide enhanced lactic acid build-up (see Jie, page 1507, col. 1). In contrast, Applicants' evidence indicates the opposite, namely that lactic acid decreases while other short chain fatty acids, e.g., butyrate, increase with

polydextrose uptake (Example 2, last paragraph on page 21). Accordingly, the method encompassed by the claims, i.e. treating subjects with uncontrolled accumulation of lactic acid in the colon cannot reasonably be found to be taught or suggested by Jie.

Takemori focuses on preparing sugar-free confections. Takemori discloses adding polydextrose as one of several alternative dietary fibers and bulking agents. (Takemori, col. 2, last paragraph; Examples 4-5; claim 9). The Examiner alleges that although Takemori is silent regarding synergism between polydextrose and lactitol, the reference falls within the amounts given on page 16 of the instant specification. Thus, the Examiner concludes that Takemori teach administration of the same composition to the same patient population, thereby anticipating the claims.

Applicants respectfully, but earnestly, disagree with the Examiner's conclusion, especially in view of the currently amended claims. The claimed subject matter is directed toward a method of treating a serious ailment. However, it is respectfully brought to the Examiner's attention that Takemori provides no guidance on how much of a daily intake of polydextrose is considerable in order to achieve any stated specific goal or purpose, let alone the specific treatment of uncontrolled lactic acid accumulation. This lack of guidance is to be expected in view of the fact that Takemori's focus is reflected in improving the feel and taste of various confectionary compositions (see Tables 5-8). Therefore, it is respectfully submitted that Takemori cannot expressly or inherently anticipate the method of the currently amended claims.

Shaw-Craig draws upon polydextrose's known bulking properties as an appetite suppressant (Shaw-Craig, paragraph [0041]). On page 8 of the Office Action of July 25, 2008, the Examiner alleges that Shaw-Craig teaches the administration of the same composition to the same patient population recited in the claims. In response, it is respectfully submitted that Shaw-

Craig does not disclose any medical condition related to balanced or imbalanced colon fermentation, nor is it suggested. Nor are there any treatments of any kind explicitly or inherently disclosed. Accordingly, Shaw-Craig does not disclose any particular regimen even remotely resembling the claimed method and, therefore, does cannot reasonably be found to anticipate the claims.

Solomons discloses methods of measuring the kinetics of polydextrose metabolism in the intestine (Abstract). Solomons measured the rate of appearance of exhaled H₂ in the breath of subjects to whom polydextrose was administered, while in other studies, the metabolism of polydextrose in fecal extracts was explored as a function of H₂ generated (Solomons, page 586, col. 1-2). In brief, there is no disclosure of a specific condition or disorder related to imbalanced colon fermentation, nor is there an explicit or inherent method of treating such a disorder.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomons in view of Borden et al. (US 5,601,863, February 11, 1997). Solomons does not teach the use of hydrogenated polydextrose, whereas Borden et al. teach that polydextrose and hydrogenated polydextrose are both enzyme-resistant and functional equivalents as food additives [columns 1-2 and paragraph bridging columns 6-7].

In response, Applicants respectfully submit that claim 26 depends from currently amended claim 1, which is believed to overcome the cited references, including Solomons. Accordingly, the rejection over Solomons in combination with Borden is also overcome. Withdrawal of said rejection is respectfully requested.

Therefore, none of the cited references are believed to teach or suggest a method of treating a subject suffering from imbalanced colon fermentation as claimed.

Accordingly, it is respectfully submitted that the amended claims are in condition for allowance, and such action is earnestly requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Peter I. Bernstein', with a long horizontal flourish extending to the right.

Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser, P.C.
400 Garden City Plaza-Suite 300
Garden City, New York 11530
(516) 742-4343
PIB/TG:ab